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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,836	03/04/2005	Kilwon Cho	DE1615	9374

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/526,836	Applicant(s) CHO ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because the limitation that the hydrophobic block carries 1.1 functional groups is not clear, how can a functional group not be a whole number, there can only be multiple functional groups for instance 2,3,4,5..... carboxylate groups, there cannot be another number other than a whole number. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the limitation that the hydrophobic block carries 1.1 functional groups is not clear, how can a functional group not be a whole number, there can only be multiple functional groups for instance 2,3,4,5..... carboxylate groups, there cannot be another number other than a whole number. The examiner in order to expedite the examining process will simply search for a hydrophobic block carrying 1 to 30 functional groups.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-7 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cha et al. (US 5,702,717).

Cha teaches a system and method for parenteral delivery of a drug (including taxol) in a biodegradable polymer in a liquid composition, the biodegradable polymer is comprised of a block copolymer comprised of a hydrophilic B block comprised of PEG with a MW between about 1000 to 20,000 and a hydrophobic A block comprised of a poly(α -hydroxy acid) polymer, biopolymer or terpolymer which includes poly(d,l-lactide-co-glycolide) i.e. PLA-co-PGA and malic acid with a MW between about 500 and 10,000. See abstract col 7 lin 32-col 8 lin 54, col 10 lin 17-24 and claims. Regarding the limitation that the number of functional groups in the hydrophobic block is between 1-30, since Cha teaches that the hydrophobic block can comprise malic acid (functional group is a carboxylate) and the MW range is so broad (preferably 500-3,000) Cha inherently teaches the same amount of functional groups, for instance 25 malic acid units would have a MW ~2900. The limitation that the composition is a micelle composition is also met because the compositions in Cha are aqueous and the same copolymers will form micelles in the same manner as the same copolymer will inherently form micelles in aqueous solution in the same manner. Regarding claim 2 the limitation of the weight of

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the block copolymer compared to the total weight of the composition is met because Cha teaches that the block copolymer concentration can be up to about 50%, which includes applicants claimed range. Regarding the limitation in claim 14 the limitation on the concentration of the drug is met because Cha teaches that the drug can make up between about 0.1 to 10% by weight of the drug polymer combination. See col 9 lin 28-32.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al. (US 5,702,717).

Cha is disclosed above. Regarding claims 8 and 9 the Cha patent meets applicants claimed formula because Cha discloses all of the component monomers in the formula of claim 8, that is PEG-PLA-PGA-(malic acid) because as stated above Cha discloses that the hydrophobic block can comprise PLA, PGA, PLA-co-PGA and malic acid biopolymer or terpolymer. Therefore it would have been obvious to the skilled artisan that the polymer encompassed by the formula of claim 8 could be selected from the disclosure within Cha. Regarding claims 10 and 11 Cha is silent on the ratios of the concentrations of the various hydrophobic bipolymers or terpolymers in relation to one another although it is the opinion of the examiner that the skilled artisan could have selected the ratios or concentrations through routine experimental practice for instance through determination of the optimum degradation rates. See col 10 lin 25-60.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1-7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/87345, cited by applicants).

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Seo discloses a micellar solution in aqueous or body fluids comprising a hydrophobic drug i.e. paclitaxel and an amphiphilic block copolymer wherein the hydrophilic segment includes PEG with a MW between 1,000-15,000 and a hydrophobic segment comprised of copolymers of lactide and glycolide or poly(amino acid)s with a MW within 1,000-10,000, the amount of drug and block copolymer are within applicants claimed range. See abstract, pag 2 lin 12-17, pag 5 lin 7-17, pag 6 lin 17-pag 7 lin 14, pag 8 lin 17-19 and pag 10 lin 14-pag 11 lin 3. Regarding the limitation that the hydrophobic polymer contains 1-30 functional groups, this claim is met by Seo because the reference discloses several hydrophobic polymers that have functional groups that would remain after the monomers were polymerized, for instance the 20 naturally occurring amino acids can contain thiol, amine and hydroxyl groups attached to their backbone. The limitation that the hydrophobic block contains 1-30 functional groups is also met because the MW range of the hydrophobic block within Seo is quite large 1,000-10,000 Daltons, for instance a polylysine hydrophobic segment with 10 monomers would have a MW of ~1300, meeting applicants limitation. Therefore it would have been obvious to the skilled artisan that the polymer encompassed by claim 1 could be selected from the disclosure within Seo.


Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER